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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

July 7, 1998

Ref: 98-DAL-WL-42

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John R. Jenen, President
Option Care Home Medical Equipment
6666 South Sheridan, Suite 100
Tulsa, Oklahoma 74133-1750

Dear Mr. Jenen:

During a May 18, 19, and 21, 1998, inspection of your medical gas manufacturing and transfilling facility, a Food and Drug Administration (FDA) investigator found serious violations of the Federal Food, Drug, and Cosmetic Act (the Act).

Specifically, your medical Oxygen U.S.P. products are adulterated within the meaning of Section 501(a)(2)(B) of the Act, in that the controls used for the manufacture, processing, packing, or holding of the drugs are not in conformance with Current Good Manufacturing Practice (CGMP) Regulations as prescribed by Title 21, Code of Federal Regulations, (21 CFR), Parts 210 and 211, as follows:

- Failure to assay the incoming liquid Oxygen U.S.P. to be used in transfilling home vessels, for identity and strength [21 CFR 211.165(a)].

- Failure to establish written procedures designed to assure that the drug products you manufacture have the identity and strength they purport or are represented to possess [21 CFR 211.100(a)].

- Failure to identify home Oxygen vessels with lot or control numbers that permits determination of the history of the manufacture and control of the batch of liquid Oxygen used [21 CFR 211.130(c)].

- Failure to properly maintain and calibrate the [redacted] Oxygen analyzer used for the assay of Oxygen U.S.P., in that the device was inoperable, and the operator's manual could not be located [21 CFR 211.160(b)(4)].

- Failure to establish written procedures for receiving and reviewing complaints [21 CFR 211.198].

- Failure to establish batch production and control records for each batch of liquid Oxygen produced, including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished [21 CFR 211.188(b)].

- Failure to provide adequate training for employees that perform the liquid and compressed Oxygen gas transfilling operations [21 CFR 211.25(a)].

- Failure to perform calibration of the Oxygen analyzer, scales, and gauges used in the liquid Oxygen manufacturing process [21 CFR 211.194(d)].

The above identification of violations is not intended to an all-inclusive list of violations and deficiencies that may exist. It is your responsibility to ensure that all requirements of the Act and regulations promulgated thereunder, are being met at your medical gas manufacturing and transfilling operation.

We request that you take prompt action to correct these violations. Failure to achieve prompt correction may result in enforcement action being initiated by FDA without further notice. These actions may include seizure of violative product, and/or injunctive action against you and your firm. Until such violations are corrected, federal agencies will be informed that FDA recommends against the award of contracts for your medical gas products.

Please notify this office in writing, within fifteen (15) working days of your receipt of this letter, stating the action you will take to assure complete compliance with the Good Manufacturing Practice Regulations. Your response should include any documentation of corrective action you have taken to correct the violations encountered at the time of the inspection.

Please direct your response to Reynaldo R. Rodriguez, Jr., Compliance Officer, at the above address.

Sincerely,

Robert D. Deininger for
Joseph R. Baca
Dallas District Director

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